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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97 N-0524]

Food Labeling: Warning and Notice Statement; Labeling of Juice Products; Technical Scientific Workshops; Requests for Additional Time to Achieve the Pathogen Reduction Standard

AGENCY: Food and Drug Administration, HHS.

ACTION: Technical scientific workshops; requests for additional time to achieve the pathogen reduction standard: rule related.

SUMMARY: The Food and Drug Administration (FDA) is announcing two technical scientific workshops to discuss and clarify issues related to the implementation of the agency's rule requiring a warning statement for certain juice products. In particular, the workshops will address the pathogen reduction interventions that have been developed for citrus juice production and the methods for measuring and validating such systems. FDA is also announcing a process by which individual manufacturers of citrus juices may request additional time, beyond the current compliance date of November 5, 1998, to implement a validated system of control measures that achieves the required reduction in pathogenic microorganisms. Manufacturers who implement such control measures will not be required to use the warning statement on their juice products. These actions are being taken in response to requests from several fresh citrus juice manufacturers that have indicated they want to implement improved controls but need additional time to do so.

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DATES: The technical scientific workshops will be held on November 12, 1998, and on November 19, 1998. Both workshops will be from 8:30 a.m. to 5:30 p.m. Registration for the workshops will be provided on a first come, first served basis and must be received by November 6,1998

Individual fresh citrus juice producers may request additional time to comply with the pathogen reduction standard in § 101.10 (21CFR 101, lo) until December 19, 1998. For requests for additional time, see the FDA District Directors listed under the **SUPPLEMENTARY** INFORMATION section of this document.

ADDRESSES: The technical scientific workshops will be held at the following locations:

The November 12, 1998, workshop will be held at the Citrus Research and Education Center. University of Florida, Lake Alfred, FL 33850, 941-956–1 151 and

the November 19, 1998, workshop will be held at the FDA District Office, 19900 MacArthur Blvd., suite 300, Irvine. C,4 90015-2486, 949-252-7592.

For requests for additional time, see the FDA District Directors listed under the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT:

To register for a technical workshop, please contact Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–22), Food and Drug .Administration, 200 C St. SW., Washington, DC 20204, 202–205--4251, FAX 202–2054970 or e-mail ''cderoeve @bangate.fda.gov''. Registration information (including name, title, firm name, address, telephone and fax numbers) must be received no later than November 6, 1998.

For information on requests for additional time to achieve the pathogen reduction standard, please contact, as listed in the SUPPLEMENTARY INFORMATION section of this document, the Director of the FDA District Office in which the firm is located.

If you need special accommodations due to a disability, please contact Catherine M. DeRoever at the previous address at least 7 days in advance.

Interested persons should note that additional information regarding the technical scientific workshops, making requests for additional time and other relevant information will be posted on CFSAN's web site, "www.cfsan.fda.gov," as it becomes available. Accordingly, such persons may wish to visit that web site on a regular basis until the workshop convenes.

SUPPLEMENTARY INFORMATION: Requests by individual citrus firms for additional time to implement control measures and validate that the process achieves the pathogen reduction in §101. lo should be addressed to the Director of the FDA District in which the firm is located, For firms in Florida, Texas, Arizona, and California the addresses are:

Douglas Tolen, District Director, FDA Florida District Office, 7200 Lake Ellenor Dr., suite 120, Orlando, FL 32809, 407–475–4702;

Joseph Baca, District Director, FDA Dallas District Office, 3310 Live Oak St.. Dallas, TX 75204, 214–655–5315; or

Elaine C. Messa, District Director, FDA Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612–2445, 7 14–798–77 14.

In the **Federal Register** of July 8, 1998 (63 FR 37030), FDA published a final regulation that requires a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present in such juices. The regulation provides that the warning statement requirement does not apply to a juice that has been processed in a manner that will produce, at a minimum, a reduction in the pertinent microorganism of at least a 5-log magnitude (i.e., 100,000 fold). In the preamble to the proposed rule (63 FR 20486, April 24, 1998), FDA recognized that pasteurization is a process that can produce the 5-log reduction. The agency also noted that manufacturers may be able to use other technologies and practices, individually or in combination (such as a combination of eliminating use of drops, brushing, washing and using sanitizers) to achieve the 5-log reduction, provided that the manufacturer's process is validated to achieve the 5-log reduction in the target microorganism.

In the preamble to the final regulation, FDA stated its expectation that citrus juice processors should be able to achieve and validate a 5-log reduction without pasteurization (63 FR 37030 at **37042).** FDA also indicated that it would be willing to meet with manufacturers or groups of manufacturers to discuss and evaluate their proposed processes. In addition, FDA stated that in order to help processors meet the pathogen reduction standard, the agency would make available, in accordance with 21 CFR part 20 of its regulations, information received by the agency regarding processes that have been validated to achieve a 5-log reduction.

FDA has received requests from several manufacturers of fresh citrus juice for 18-additional months beyond the November 5, 1998, compliance date for the warning statement requirement to permit such firms to develop and to validate procedures that will achieve the 5-log reduction in citrus juices. In discussions with the agency, there was evidence of widespread confusion among juice manufacturers as to how FDA expects the 5-log reduction to be achieved.

Upon consideration of the fresh citrus juice manufacturers' request and in light of other information before the agency regarding progress made by some citrus juice manufacturers in identifying effective mechanisms for pathogen reduction, FDA has developed a two-part strategy to respond to these requests. First, FDA will sponsor two technical scientific workshops for the citrus juice industry, open to the public, on November 12 and November 19, 1998. Each workshop will include a discussion of the control measures of which FDA is aware that are being used for citrus juice production and of the methods for measuring and validating the effectiveness of the measures in reducing pathogens. FDA believes that these workshops will provide an opportunity for industry representatives and other members of the public to share information regarding control measures that are believed to achieve the 5-log reduction. Participants are requested to bring to the workshop at least 150 copies of any written or published materials they wish to distribute at the workshop. Agency experts will be available to answer technical questions.

Second, as noted, several firms have requested that FDA extend the final rule's compliance date for citrus juices to permit those firms additional time to develop and validate intervention

measures that achieve the 5-log pathogen reduction standard. FDA believes that a formal extension of the rule's compliance date is not feasible in the current circumstances because such extension would arguably require notice and comment rulemaking. Nevertheless, FDA believes that under certain conditions (which are enumerated as follows), it would be an appropriate exercise of the agency's enforcement discretion to suspend enforcement of the final rule for a limited period of time. In particular, FDA will consider such an exercise of its enforcement discretion for those citrus juice producers who no later than December 19, 1998, request such consideration and who make the following commitments in writing:

(1) The firm agrees to use the time period between November 4, 1998, and July 8, 1999. to develop, adapt, and validate procedures that are sufficient to achieve a 5-log reduction in the pertinent microorganism; and,

(2) The firm agrees to establish interim protection measures in the form of a system that applies hazard analysis and critical control point (HACCP) principles. This interim system will include. at a minimum, good manufacturing practices and specific control measures such as chemical washing and brushing of the fruit, sanitizing, culling of damaged fruit, and utilization of only those types of fruit with skins that are sufficiently smooth and durable to be cleanable and to remain intact after cleaning; and.

(3) The firm agrees to comply with the provisions of the warning label regulation (§ 101.17 (g)) no later than July 8, 1999. As a result of this commitment, the firm will use the warning label on its products beginning July 8, 1999, if it has been unable to implement validated control measures that achieve the 5-log reduction.

FDA believes that this two-part strategy is reasonable and will provide appropriate public health protection. As noted in the warning statement rulemaking, because the warning statement provides consumers with important information about the risk of foodborne illness, the warning requirement contributes to public health protection in that it allows consumers to make informed purchase decisions. In FDA's view, this warning statement requirement is primarily an interim

step designed to reduce the risk of fresh juice consumption pending completion of a final HACCP rule and its implementation. However, because the warning statement requirement may nevertheless allow contaminated juice products to reach the marketplace, FDA does not expect the statement to be as effective in protecting consumers as would a validated 5-log reduction program. FDA believes it is appropriate to consider exercising its enforcement discretion where, as a result of such exercise, the agency can provide an incentive for citrus juice processing firms to produce safe juice earlier than such firms would otherwise do.

Because of the relationship between particular provisions in the warning statement regulation and the HACCP proposal, FDA is announcing its intention to reopen the comment period on the juice HACCP proposal (63 FR 20450) entitled ''Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and importing of Juice. " This reopening will allow information and data presented at the workshop to be included in the record of the HACCP rulemaking. A **Federal Register** document announcing the reopening of the juice HACCP proposal comment period will be published at a later date.

Transcripts of the workshops will be prepared. Copies of the transcripts may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15-working days after the meetings at a cost of 10 cents per page.

Dated: October 23, 1998

William B. Schultz

William B, Schultz
Deputy Commissioner for Policy

[FR Dec. 98-'???'? Filed '??-'? ?-9S; 8:45 am]

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